

# Vaccines for Children Program Enrollment Information



Thanks for your interest in our program.  
Please call with questions.

**Missouri Department of Health & Senior Services  
Bureau of Immunization Assessment & Assurance  
Section for Disease Control & Environmental Epidemiology**

**VFC CONTACT INFORMATION:  
P.O. Box 570 Jefferson City MO 65102-0570**

**PHONE: 800-219-3224 FAX: 573-526-5220**

# PROVIDER ENROLLMENT CHECKLIST

In order to enroll in the VFC Program, the following **must** be completed and returned to the VFC Program:

- VFC Provider Enrollment Agreement form (initial and sign as indicated)
- VFC Program Provider Enrollment
- Copy of the Missouri Vaccines for Children Vaccine Loss and Replacement Protocol (page 5, the signature page)
- Copy of your clinic's emergency procedures for vaccine storage, handling and/or relocation in the event of power loss or refrigeration/freezer failure
- Copy of the Provider Refrigerator and Freezer Information Sheet

In addition, all VFC providers must also submit the following:

- The current manufacturer certification for each thermometer used in your clinic
- At least 2 weeks of temperature logs checked twice daily and entered on a temperature log.

VFC Providers must participate in a minimum of one approved educational opportunity such as Missouri's Vaccine University to enhance their knowledge of the VFC program and immunizations.

Mail or FAX these items to:

**VFC Program**  
**Missouri Department of Health and Senior Services**  
**930 Wildwood, PO Box 570**  
**Jefferson City, MO 65102**  
**FAX: 573-526-5220**

## VACCINES FOR CHILDREN PROGRAM ENROLLMENT

- ❖ By signing the **VFC Provider Enrollment Agreement** form, you agree to participate in the program and follow the requirements outlined in the Omnibus Budget Reconciliation Act (OBRA), which are listed on the form.
- ❖ The **VFC Program Provider Enrollment** form provides shipping and mailing information and helps the State to determine the amount of vaccine to be supplied through the VFC program. This form may also be used to compare estimated vaccine needs with actual vaccine supply. This form is also used to list required information for all providers in your practice who will administer VFC vaccines. This information is also necessary if you wish to bill Medicaid for the vaccine administration fee.
- ❖ The **Loss and Replacement Protocol** information is used for management of incidents that result in loss of vaccine supplied by Missouri Vaccines for Children program. By signing this document you are stating you have read and agree to the statements.
- ❖ An **Emergency Plan/Power Outage Plan** is used in case of an emergency/power outage situation so your staff will know where to store the vaccines and who to contact.

These forms are enclosed with this packet. Instructions are shown on the reverse side of the forms. Completed forms may be sent by mail or FAX to:

**Missouri Department of Health and Senior Services  
Vaccines for Children Program  
P. O. Box 570  
Jefferson City, MO 65102-0570  
FAX: (573) 526-5220**

We will make every attempt to process your enrollment forms within one week of receipt. Once you are enrolled, the Immunization Quality Manager in your area will deliver your VFC provider packet and conduct an in-service on VFC Procedures. Your refrigerator and freezer temperatures will be checked.

Refrigerator stable vaccine needs to be stored between 35°-46° F (2°-8° C). Vaccines required to be stored in freezers must be stored at 5° F (-15° C) or colder. Providers should check the adequacy of their storage units before obtaining vaccine. The Immunization Quality Manager must validate that the refrigerator and freezer temperatures are acceptable before vaccine orders may be placed. Please see Refrigeration Requirements for Enrollment/Re-enrollment in the VFC Program.

# *VACCINES FOR CHILDREN (VFC) PROGRAM OVERVIEW*

## **1. What is the VFC Program?**

The Omnibus Budget Reconciliation Act (OBRA) created the Vaccines for Children (VFC) Program as Section 1928 of the Social Security Act on August 10, 1993. The VFC Program, which began October 1, 1994, represents an unprecedented approach to improving vaccine availability nationwide by providing vaccine free of charge to VFC-eligible children through public and private providers.

The VFC Program:

- ❖ Provides publicly purchased vaccine, for eligible children, **at no charge** to public and private providers in all states, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, Guam, and the Commonwealth of the Northern Mariana Islands.
- ❖ Automatically covers vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) and approved by the Centers for Disease Control and Prevention (CDC).
- ❖ Saves parents and enrolled providers out-of-pocket expenses for vaccine.
- ❖ Eliminates vaccine cost as a barrier to immunizing VFC-eligible children.
- ❖ Discourages the practice of referring children from the private sector to the public sector for vaccination, thereby keeping children in their medical home for comprehensive health care and reducing missed opportunities for vaccination.

By eliminating cost as a barrier to immunizing children and providing opportunities for vaccinations at many health provider locations, the VFC program supports improved immunization coverage levels among eligible children.

**The goal is to ensure that no VFC-eligible child contracts a vaccine-preventable disease because of his or her parent's inability to pay for the vaccine or vaccine administration.**

## **2. Who can receive VFC vaccine?**

The children who can get VFC vaccine are those children from birth through 18 years old who:

- ❖ Are eligible for Medicaid
- ❖ Have no health insurance
- ❖ Are Native American or Alaska Native, or
- ❖ Have health insurance, but it does not cover immunizations, AND they go to a Federally Qualified Health Center (FQHC) or Rural Health Center (RHC)

### 3. What are the VFC Program requirements for providers?

To participate in the VFC program, providers agree to:

- ❖ Complete the updated VFC Program Provider Re-enrollment on an annual basis.
- ❖ Screen the patient or guardian to determine the child's eligibility (verification is not required). The screening record will be stored for a period of 3 years, after service to the patient has been completed. Screening records will be shown to state immunization program staff or those representatives designated by the state upon request.
- ❖ Administer VFC vaccines only to children in eligible age cohorts for each vaccine, as set by the Advisory Committee on Immunization Practices (ACIP) in VFC resolutions.
- ❖ Comply with the recommended immunization schedule, dosage, and contraindications, established by the ACIP and state law.
- ❖ Provide current Vaccine Information Statements and maintain records in accordance with the National Childhood Vaccine Injury Act, which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).
- ❖ Charge a vaccine administration fee that is not above the regional fee cap of \$15.07 established by the Centers for Medicare and Medicaid Services (CMS).
- ❖ Immunize eligible children with VFC-supplied vaccine at no charge to the patient for the vaccine.
- ❖ Comply with the state's requirement for eligibility screening, vaccine ordering, and vaccine accountability.
- ❖ Comply with the state's requirements for vaccine storage and handling.
- ❖ Maintain documentation of VFC vaccines administered, eligibility records, and temperature logs for a period of 3 years, unless State requirements call for a longer duration.
- ❖ Submit vaccine usage and inventory reports that document VFC eligibility and doses administered data monthly.
- ❖ Submit temperature logs monthly.
- ❖ Make records available for review to public health officials and program representatives as requested.

Missouri providers may collect an administration fee up to **\$15.07** for non-Medicaid VFC eligible children, although lower fees are encouraged. The fee can be charged for each dose given. VFC providers may also charge an office visit fee. Private providers do not have to accept patients just because they are VFC eligible.

In no case may a Medicaid provider impose an additional vaccine administration charge to a parent for services rendered to a Medicaid child. This prohibition also applies to “donations” requested by a public health facility.

Providers should contact Medical Services or Medicaid managed care for questions related to administration fees for Medicaid-eligible children.

**NO PROVIDER MAY DENY VFC VACCINE TO VFC-ELIGIBLE PATIENTS BECAUSE THEY ARE UNABLE TO PAY THE ADMINISTRATION FEE.**

**4. What are the VFC Program equipment requirements for providers?**

To participate in the VFC program, providers agree to:

- ❖ Purchase or possess a certified calibrated thermometer for each refrigeration unit storing VFC vaccine and send a copy of the certificate to the VFC program.
- ❖ Submit two (2) weeks of temperature readings, that have been checked twice daily and entered on a temperature log, to the VFC program.
- ❖ Purchase or possess stand-alone refrigeration units. Stand-alone refrigeration units are the standard reflecting ACIP’s preference for **single refrigeration** or **single freezer** units over combination “household” units. Check with the manufacturer to ensure the temperature can be maintained properly. Consider purchasing a chest type freezer as it does not fluctuate as much as a side door opening freezer.
- ❖ For high-volume practices with large vaccine storage needs, a purpose-built refrigeration unit manufactured specifically for storing biologicals may be recommended. All under-the-counter refrigeration units **must** be “bio-medical” or “purpose built” (manufactured specifically for the purpose of holding biological).
- ❖ All units must maintain proper temperatures (measured by a current certified, calibrated thermometer), be large enough to hold the year’s largest inventory, and be certified by a VFC program representative before starting the program and periodically thereafter.

Temperatures:

- a. Refrigerators: 35 to 46°F or 2 to 8°C (refrigerator temperatures preferably kept in the mid-temperature range). **Colder** is **not** better. Store around 40°F or 4°C.
  - b. Freezers: 5°F or colder or -15°C or colder, i.e., -16°C -17°C -18°C etc. (Freezer temperatures preferably kept below these temperatures. Here colder **is** better).
- ❖ All providers may be asked to place temperature data recording devices in their refrigerators and freezers periodically. At that time you will be instructed on where and how to place the devices, as well as when and how to return the devices to DHSS.

**Vaccines for Children Program**  
**Missouri Department of Health and Senior Services**  
**PO Box 570, Jefferson City, MO 65102-0570**  
-Or-  
**Fax: (573) 526-5220**

## *VACCINES CURRENTLY PROVIDED THROUGH THE VFC PROGRAM*

The Omnibus Budget Reconciliation Act of 1993 (43 U.S.C. 1396s) conferred an operational role on the Advisory Committee on Immunization Practices (ACIP) to establish a list of vaccines for administration to children eligible to receive vaccines through the Vaccines for Children (VFC) Program, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to pediatric vaccines.

VFC vaccine must be administered according to the guidelines outlined by the ACIP in the VFC resolutions. Vaccines provided through the VFC Program include:

### **DT**

- Provided to VFC-eligible children younger than 7 years of age, if pertussis vaccine is contraindicated.

### **DTaP**

- Provided to VFC-eligible children 6 weeks through <7 years of age. The vaccine is approved for all doses of the DTP series.

### **DTaP/HB/IPV**

- Provided to VFC-eligible children 6 weeks through <7 years of age. The combined vaccine is approved for the primary series (Doses 1-3) only.

### **DTaP/Hib/IPV**

- Provided to VFC-eligible children 6 weeks through <7 years of age. The combined vaccine is approved for the primary series.

### **DTaP/IPV**

- Provided to VFC-eligible children ages 4 years to 6 years. The combined vaccine is approved for the 5<sup>th</sup> dose of the DTaP series and the 4<sup>th</sup> dose of the IPV series.

### **EIPV**

- Provided to VFC-eligible children 6 weeks through 18 years of age.

### **Hep A**

- Provided to VFC-eligible children who are 1 year through 18 years of age.

### **Hep B**

- Provided to VFC-eligible children 0 through 18 years of age.

### **Hep B/Hib**

- Provided to VFC-eligible children 6 weeks through 59 months of age. The vaccine is licensed for use at 2, 4, and 12-15 months of age.

### **Hib**

- Provided to VFC-eligible children 6 weeks through 59 months of age.

### **HPV**

- Provided to VFC-eligible **females** 9 through 18 years of age **ONLY**.

### **Influenza**

- Provided for all healthy VFC-eligible children 6 months through 18 years.

**Influenza (Live Attenuated)**

- Provided for all VFC eligible children (those who do not have an underlying medical condition that predispose them to influenza complications) aged 2 years through 18 years.

**Meningococcal (MCV4)**

- Children and adolescents aged 2-18 years who are traveling to countries in which invasive disease caused by N.meningitidis is hyperendemic or epidemic, particularly if contact with the local population will be prolonged, children with terminal complement deficiencies and those with anatomic or functional asplenia, or who are infected with HIV.
- All adolescents aged 11-18 years of age.

**MMR**

- Provided to VFC-eligible children 12 months through 18 years of age.

**Pneumococcal 23-valent (Polysaccharide)**

- Provided only to VFC-eligible children 2 years through 18 years who have functional or anatomical asplenia, immunocompromising illness or medications, chronic illness (as specified above), who are Alaska Native or American Indian, or who have received a bone marrow transplant.

**Pneumococcal 7-valent (Conjugate)**

- All infants and children at least 6 weeks of age through 59 months old. Groups identified by ACIP as being at highest risk include infants, toddlers through 24 months old, children with sickle cell disease or anatomic asplenia, chronic illnesses, immunocompromising conditions, or HIV infection. Groups at moderate risk include toddlers 24-35 months old, children of African American, American Indian, and Alaska Native descent, and children who attend out of home child care between 35 and 59 months old.

**Rotavirus**

- Provided only to VFC-eligible infants 6 weeks through 32 weeks of age **ONLY**.

**Td**

- Provided for VFC-eligible children 7 years of age or older. Recommendation at 11 years or older as a booster rather than Tdap may be indicated in some special situations (please see ACIP recommendations). May be used as early as age 7 years if needed for catch-up including for a primary series if indicated.

**Tdap**

- Provided to VFC-eligible adolescents 11 through 18 years of age. If 5 years have elapsed since the previous dose, a single booster dose is recommended.

**Varicella**

- Provided to VFC-eligible children who are at least 12 months of age through 18 years.



## ELIGIBILITY

Federally purchased vaccine is available at no charge through the VFC program to public and private providers for eligible children. Children ages 0 through 18 years who meet at least one of the following criteria are eligible for VFC vaccine.

- ❖ Medicaid Enrolled: A child enrolled in the Medicaid program
- ❖ Uninsured: A child who has no health insurance coverage
- ❖ American Indian/Alaska Native: As defined by the Indian Health Services Act

### FQHC/RHC FACILITIES ONLY

- ❖ Underinsured: Underinsured is defined as children who have commercial (private) health insurance but the coverage does not include vaccines, children whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only), or children whose insurance caps vaccine coverage at a certain amount – once that coverage amount is reached, these children are categorized as underinsured. Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC).

Example of vaccine cap: Insurance covers the first \$100.00 for vaccines. Once that is met, any additional cost for vaccine is considered an out-of-pocket expense. At that time, the child is eligible for VFC vaccine.

Children **NOT considered underinsured**: Children whose health insurance covers the cost of vaccinations, but because of a **high un-met deductible** a claim would be denied.

**FQHC** — A center that provides health care to a medically underserved population may apply to the Bureau of Primary Health Care/Health Resources Services Administration (HRSA) for FQHC status. If the application is approved and the center meets HRSA qualifications, FQHC status is conferred. FQHCs include community and migrant centers, special health facilities such as those for the homeless and persons with AIDS that receive grants under the PHS Act, and “look-alikes” that meet the qualifications but do not actually receive grant funds. They also include health centers within public housing and Indian health centers. Contact the Missouri Primary Care Association at 573-636-4222 for eligibility questions.

**RHC** — The Rural Health Clinic program was established to increase care for rural underserved communities and to expand the use of nurse practitioners (NPs), physician assistants (PAs), and certified nurse midwives (CNMs) in rural communities. To be eligible for certification as an RHC, a clinic must be located in a Health Professional Shortage Area, Medically Underserved Area, or a Governor Designated Shortage Area. RHCs are required to be staffed by PAs, NPs, or CNMs at least half of the time the clinic is open. Contact the Department of Health and Senior Services at 573-751-6303 for eligibility questions.

## MONTHLY DOCUMENTATION

### ❖ *Vaccine and Patient Accountability*

In order to comply with General Accounting Office (GAO) regulations, you will need to maintain accountability of the VFC patients you see and the types of vaccine administered. We will send you a tally sheet to gather this information once you are enrolled in the VFC program. With the exception of your first order, you will need to submit a summary of the accountability information with your orders before they can be filled.

### ❖ *Ordering Vaccines*

When placing an order, you will use the Missouri Immunization Program Vaccine Order Form included in your new provider packet. VFC orders are accepted by mail or fax. Participation in the VFC program will have no impact on the vaccines you purchase for your private-pay patients. Vaccines ordered through the program do not need to be stored in a separate refrigerator or freezer; however, VFC vaccines should not be intermingled with private stock or other vaccines purchased from the state. Providers must offer and order all ACIP recommended vaccines. Providers are requested to order and maintain a 30-45 day supply of vaccine.

### ❖ *Temperature Logs*

The Vaccines for Children program requires providers to check temperature twice daily and record the temperature. Each week the temperature log needs to be signed by a supervisor or representative for the facility showing the temperature are within range and if there was a problem corrective action had been taken. The temperature records are to be sent in with the monthly vaccine accountability and order form.



MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES  
**VACCINES FOR CHILDREN (VFC) PROGRAM PROVIDER  
ENROLLMENT / RE-ENROLLMENT FORM**

For State Use Only  
Date Certified

All public and private health care providers participating in the Vaccines for Children (VFC) program must complete this form annually. This document provides shipping and mailing information and helps the State determine the amount of vaccine to be supplied through the VFC program. This form also may be used to compare estimated vaccine needs with actual vaccine supply. The enrollment/ reenrollment form must be updated annually or more frequently if: 1.) the number of children being served changes, or 2.) the status of the facility changes (i.e., FQHC or RHC becomes a private provider).

(See Page 3 Instructions – Please Print)

PIN

**PRACTICE INFORMATION/SHIPPING**

FACILITY/CLINIC NAME		COUNTY	
VACCINE DELIVERY/SHIPPING ADDRESS (NO PO Box)		CITY	STATE ZIP
VACCINE DELIVERY CONTACT PERSON(S) (first, last name and title) 1 _____ 2 _____		CONTACT PERSON(S) DIRECT PHONE _____ _____ EXT _____	
FAX	OFFICE E-MAIL ADDRESS		
SUPERVISOR OF VACCINE DELIVERY CONTACT PERSON(S)			
PERSON RESPONSIBLE FOR BILLING (first, last name and title)		PERSON RESPONSIBLE FOR ESTABLISHING THE COST OF ADMINISTRATION (first, last name and title)	

LIST TIMES THAT STAFF ARE AVAILABLE (**MONDAY THROUGH FRIDAY**) TO RECEIVE VACCINE IN YOUR FACILITY

Monday \_\_\_\_\_ Tuesday \_\_\_\_\_ Wednesday \_\_\_\_\_  
Thursday \_\_\_\_\_ Friday \_\_\_\_\_

PROVIDER TYPE	SPECIALTY or SPECIALTY CLINIC TYPE?
<input type="checkbox"/> Public Health Department <input type="checkbox"/> Private Practice <input type="checkbox"/> Private Hospital <input type="checkbox"/> Federally Qualified Health Center <input type="checkbox"/> Other Public _____ <input type="checkbox"/> Other Private _____ <input type="checkbox"/> Rural Health Center	<input type="checkbox"/> Pediatric <input type="checkbox"/> Family Practice <input type="checkbox"/> OB/GYN <input type="checkbox"/> Family Planning <input type="checkbox"/> Multispecialty <input type="checkbox"/> Other _____

**MAILING ADDRESS**

CONTACT PERSON			
MAILING ADDRESS		CITY	STATE ZIP

**VACCINE STORAGE UNITS**

INDICATE YOUR REFRIGERATOR STORAGE UNIT TYPES BELOW:		INDICATE YOUR FREEZER STORAGE UNIT TYPES BELOW:	
TYPE	NUMBER OF UNITS	TYPE	NUMBER OF UNITS
<input type="checkbox"/> Small/Under Counter	_____	<input type="checkbox"/> Small/Under Counter	_____
<input type="checkbox"/> Stand Alone	_____	<input type="checkbox"/> Stand Alone	_____
<input type="checkbox"/> Combination	_____	<input type="checkbox"/> Combination	_____
<input type="checkbox"/> Commercial/Pharmacy Grade	_____	<input type="checkbox"/> Commercial/Pharmacy Grade	_____
		<input type="checkbox"/> No Varicella	

# VACCINES FOR CHILDREN (VFC) PROGRAM PROVIDER ENROLLMENT / RE-ENROLLMENT FORM

PIN

## PATIENT ESTIMATES

1. Estimate the number of children who will receive immunizations at your practice or clinic for a 12-month period, by category:	Ages (Note: Do not count a child in more than one category.)				TOTAL
	<1 year	1-6 years	7-18 years	>18 years (non VFC Vaccine)	
a. Medicaid Eligible					
b. No Health Insurance					
c. American Indian or Alaskan Native					
d. Underinsured <b>(FQHC/RHC only)</b> Health insurance but coverage does not include vaccinations, includes only select vaccinations, or has a vaccination cost limit.					
e. Eligible for non-VFC vaccine <b>(LPHAs only)</b>					
<b>TOTAL VFC - Eligible</b>					

2. Indicate the number of children who are or will be two years of age during this calendar year. \_\_\_\_\_

3. Indicate if this facility/clinic immunizes children 11-18 years of age: ☐ Yes ☐ No

4. Estimate the % of patients 0-18 years who are VFC eligible. \_\_\_\_\_

Type of data used to determine projections:

☐ Benchmarking Data (see instructions for details)

☐ Provider Encounter Data

☐ Medicaid Claims Data

☐ Vaccine Replacement Data

☐ Registry Data

☐ Prior Ordering Data

## LIST OF HEALTH CARE PROVIDERS WHO ADMINISTER VFC PROGRAM-PROVIDED VACCINE

Instructions: Complete the fields below for each provider who will be administering VFC vaccine to VFC-eligible children at this facility. Include identifying information for all providers/clinics whose NPI number will be used for billing. Information should also be included for the physician who supplies the standing orders or collaborative practice. Attach additional sheets if necessary.

Last , First Name	Title	Medical License Number	Nurse/Physician NPI number	Facility NPI number	Specialty

## E-MAIL COMMUNICATION

To keep up with changing needs of our providers, the Missouri VFC Program is planning for future methods of communicating with providers. E-mail communication would be more timely – immediate compared to several days for a BlastFAX or regular mail – and involve less paper to file.

If your practice would be interested in receiving VFC Program communications by e-mail, signify your interest by entering your preferred e-mail address on the line below.

Preferred E-mail Address for VFC Communication: \_\_\_\_\_

If your practice is interested but does not currently have an e-mail address, check this box: ☐

Signature of Clinic Director/Immunization Director

Date

Return completed form to: **Department of Health and Senior Services  
Vaccines for Children Program  
PO Box 570  
Jefferson City, MO 65102-0570**

or FAX to: **573-526-5220**

## VACCINES FOR CHILDREN (VFC) PROGRAM PROVIDER ENROLLMENT / RE-ENROLLMENT FORM INSTRUCTIONS

All VFC providers must submit an Enrollment/Re-enrollment form annually to update **staffing** and **shipping** information.

A. **PIN:** Print the PIN of the facility/clinic.

### PRACTICE INFORMATION/SHIPPING

B. **FACILITY/CLINIC NAME:** Print the name of the facility/clinic.

C. **COUNTY:** Print the name of the county where the facility is located.

D. **VACCINE DELIVERY/SHIPPING ADDRESS:** Print the street address, city, state and zip where the vaccine will be shipped. Vaccines CANNOT be delivered to a P.O. Box. If you do not have a standard street address, list a street location for delivery (for example, Corner of First and Main).

E. **VACCINE DELIVERY CONTACT PERSON(S):** Print the first and last name and the title of the person(s) who will manage the VFC vaccine supply and who will be available to accept deliveries and/or answer questions regarding VFC vaccine orders (for example, the office manager, head nurse, pharmacist, etc.).

F. **CONTACT PERSON(S) DIRECT PHONE:** Print the direct office phone number and extension for the primary VFC contact person.

G. **FAX:** Print the current FAX number for the facility/clinic.

H. **OFFICE E-MAIL ADDRESS:** Print the facility/clinic e-mail address of the primary or secondary VFC contact.

I. **SUPERVISOR OF VACCINE DELIVERY CONTACT PERSON(S):** Print the first and last name of the supervisor(s) of the Vaccine Delivery Contact Person(s).

J. **PERSON RESPONSIBLE FOR ESTABLISHING THE COST OF ADMINISTRATION:** Print the first and last name and the title of the person who has responsibility for determining the amount of the administrative fee charged by the clinic.

K. **PERSON RESPONSIBLE FOR BILLING:** Print the first and last names and the title of the person who has responsibility for billing for the clinic.

L. **LIST TIMES THAT STAFF ARE AVAILABLE (MONDAY-FRIDAY) TO RECEIVE VACCINE IN YOUR FACILITY:** Print all times staff in your facility is available for vaccine delivery Monday through Friday. Print times office is closed for lunch if applicable.

M. **PROVIDER TYPE:** Check the provider type that best describes your facility/clinic.

N. **SPECIALTY OR SPECIALTY CLINIC TYPE:** Check the specialty that best describes your practice.

### MAILING ADDRESS

O. **CONTACT PERSON:** Print the first and last name of the person who should receive informative mailings from the Department.

P. **MAILING ADDRESS:** Print the address, city, state and zip where mail is delivered.

### VACCINE STORAGE UNITS

Q. **INDICATE YOUR REFRIGERATOR STORAGE UNIT TYPES BELOW:** Check the type(s) of refrigeration units your facility will use to store VFC vaccine and indicate how many of each type of unit(s).

R. **INDICATE YOUR FREEZER STORAGE UNIT TYPES BELOW:** Check the type(s) of freezer units your facility will use to store VFC vaccine and indicate how many of each type of unit(s).

### PATIENT ESTIMATES

S. **ESTIMATE THE NUMBER OF CHILDREN WHO WILL RECEIVE IMMUNIZATIONS AT YOUR FACILITY/CLINIC FOR A 12 MONTH PERIOD, BY CATEGORY:** Print the number of children who will receive immunizations at your facility/clinic for a 12 month period. Break this down by age (<1, 1-6 years, and 7-18 years) and by eligibility criteria (Medicaid Eligible, No Health Insurance, American Indian or Alaskan Native, or Underinsured). LPHAs ONLY: Indicate the number of children and adults who are eligible to receive non-VFC vaccine.

T. **INDICATE THE NUMBER OF CHILDREN WHO ARE OR WILL BE TWO YEARS OF AGE DURING THIS CALENDAR YEAR:** Print the number of children seen at this facility/clinic who are two years of age or will turn two years of age during the current calendar year.

U. **INDICATE IF THIS FACILITY/CLINIC IMMUNIZES CHILDREN 11-18 YEARS OF AGE:** Check Yes or No

V. **ESTIMATE THE % OF PATIENTS 0-18 YEARS WHO ARE VFC ELIGIBLE:** Print the estimated percentage of patients, age 0-18 years, seen at this facility/clinic that is currently VFC eligible.

W. **TYPE OF DATA USED TO DETERMINE PROJECTIONS:** Check the type of data used to project the number of VFC-eligible children who will receive immunizations at this clinic during the upcoming year. With the benchmarking approach, the provider maintains a log in which all doses administered for a predetermined period of time are recorded. Typically, this information is gathered for a very limited period of time (2-3 months); include a month when the clinic is very busy immunizing children and a month that the clinic immunizes fewer children. The benchmarking log includes a child's VFC eligibility status by specific category and type of vaccine administered. This data then forms the basis by which a provider's vaccine needs for the year are prorated.

### LIST OF HEALTH CARE PROVIDERS WITH PRESCRIPTION WRITING PRIVILEGES

X. **COMPLETE** the fields for each provider who will be administering VFC vaccine to VFC-eligible children at this facility. Include identifying information for all providers/clinics whose NPI number will be used for billing. Information should also be included for the physician who supplies the standing orders or collaborative practice.

Y. **SIGNATURE/DATE:** Sign and date the completed enrollment/re-enrollment form.

**VFC PROVIDER ENROLLMENT AGREEMENT**For State Use Only  
Date Certified

PIN

To participate in the Missouri Vaccines for Children (VFC) Program and receive federally procured vaccine provided to my facility at no cost, I,

\_\_\_\_\_  
(Print name)

acting as the physician or administrator in charge of

\_\_\_\_\_  
(Facility Name)

will assure that all practitioners participating under this enrollment agree to:

Initials

- \_\_\_ 1. Comply with the state's requirement for VFC eligibility screening, vaccine ordering, vaccine accountability, and storage and handling, per attached protocol documents.
- \_\_\_ 2. Screen and document eligibility of patients **at each visit** and administer VFC-provided vaccine only to a child ( $\leq 18$  years of age) who qualifies in one or more of the following categories:
  - a) is on Medicaid (or qualifies through the state's Medicaid waiver);
  - b) has no health insurance (other than Medicaid);
  - c) is an American Indian or Alaskan Native; and/or,
  - d) has insurance that does not pay for the vaccine (applicable **only** to vaccines administered by **Federally Qualified Health Centers or Rural Health Centers**).
- \_\_\_ 3. Administer VFC-provided vaccines as directed by the current Advisory Committee on Immunization Practices (ACIP) and/or in accordance with VFC resolutions.
- \_\_\_ 4. Comply with the appropriate immunization schedule, dosage, and contraindications that are established by the ACIP, unless in my medical judgment and in accordance with accepted medical practice, I deem such compliance to be medically inappropriate.
- \_\_\_ 5. Provide current Vaccine Information Statements to the parent/guardian/representative of the recipient for each vaccine given and maintain records in accordance with the National Childhood Vaccine Injury Act, which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).
- \_\_\_ 6. Not impose a charge for the cost of the VFC-provided vaccine.
- \_\_\_ 7. Not impose a charge for the administration of the VFC-provided vaccine in any amount higher than \$15.07 **per injection** (the maximum fee established by the state) for non-Medicaid children. For Medicaid VFC-eligible children, accept the reimbursement for immunization administration set by the state Medicaid agency.
- \_\_\_ 8. Administer VFC-provided vaccine to a child even if the child's parent/guardian/representative of record is unable to pay the administration/office visit fee(s).
- \_\_\_ 9. Participate in an annual site visit and immunization improvement activities in collaboration with program representatives as requested.
- \_\_\_ 10. **Be responsible for the proper storage and handling of VFC-provided vaccine upon delivery to my facility and understand that I will be required to replace dose-for-dose the VFC-provided vaccine wasted due to my/our negligence (as determined by the program on a case by case basis).**
- \_\_\_ 11. Must use certified, calibrated thermometers in all refrigeration equipment containing VFC-provided vaccine (**submit a copy of the current certification for each thermometer with this form**). Use program approved temperature log(s) to record and monitor the refrigerator(s) and freezer(s) temperature(s) **at least twice daily** and submit a copy of the temperature data to the VFC program each month.

- \_\_\_12. Use only program-approved refrigerator(s) and freezer(s) for storage of vaccines. Loss of vaccine as the result of using an unapproved refrigerator or freezer (i.e., dorm-style refrigerators or single control household units) shall be deemed as negligence. (Refer to Document "Refrigeration Requirements for Enrollment/Re-enrollment").
- \_\_\_13. **Take immediate action to prevent the loss of vaccine when temperatures are out of range and document such actions.** For proper temperature monitoring, transporting and storage of vaccine during off site clinics, refer to Cold Chain Protocol (attached).
- \_\_\_14. Develop and **submit with this form** a copy of current emergency procedures for vaccine storage, handling and/or relocation in the event of power loss or refrigeration/freezer failure. (Sample template attached and guidance available upon request.)
- \_\_\_15. Maintain all records related to VFC program such as vaccines administered, documentation of eligibility, and temperature logs for a period of **three (3) years**. Release of such records will be bound by the privacy protection of Federal Medicaid law and HIPAA.
- \_\_\_16. Make such records available for review to public health officials (Missouri Department of Health and Senior Services program representatives, including the Department of Health and Human Services) as requested.
- \_\_\_17. VFC Providers of less than 2 years agree to participate in a minimum of one approved educational opportunity such as Missouri's Vaccine University to enhance their knowledge of the VFC program and immunizations. *The VFC program encourages staff in all VFC provider offices to attend immunization educational trainings annually if possible. The program recommends the following trainings: Missouri's Vaccine University, Missouri's Immunization Conference (held biennially), or the Mid American Immunization Coalition's (MAIC) Immunization Conference held biennially alternating with Missouri's Immunization Conference) and any CDC sponsored or supported immunization program.*
- \_\_\_18. Agree to operate within the VFC program in a manner intended to avoid fraud and abuse.

My staff and I have reviewed and will comply with the VFC Vaccine Loss Protocol and the VFC Cold Chain Protocol. As staff changes occur, training will be provided and documented in all aspects of VFC Program requirements. **A VFC contact and alternate shall be trained at all times.**

I will notify VFC staff with any staffing changes within the program.

I, or the Missouri Department of Health and Senior Services, may terminate this agreement at any time for personal reasons or for failure to comply with these requirements.

**NOTE: I understand that if this agreement is terminated, I must return to the VFC Program all unused (viable and non-viable) vaccine. I also will comply with the VFC Program's procedures for return of the vaccine.**

I certify that I have read and agree to the requirements listed above to participate in the Missouri Vaccines for Children Program.

---

Provider (Administrator) Signature

---

Date

**RETURN COMPLETED ORIGINAL FORM TO:**

**Vaccines for Children Program  
Missouri Department of Health and Senior Services  
PO Box 570, Jefferson City, MO 65102-0570  
-Or-  
Fax to: (573) 526-5220**

# Vaccine Loss and Replacement Protocol

## Missouri Vaccines for Children Program

### **\*\*\*POST IN A CONSPICUOUS PLACE\*\*\***

#### **Definitions**

<b>Wasted:</b>	<i>Any vaccine that cannot be used. This includes expired, non-viable and lost vaccines.</i>
<b>Expired:</b>	<i>Any vaccine with an expiration date that has passed.</i>
<b>Non-viable:</b>	<i>Any vaccine that exceeds the limits of the approved cold chain procedures or is pre-drawn and not used within acceptable time frames. <b><u>Always</u></b> consult VFC Program before determining the vaccine is non-viable.</i>
<b>Lost:</b>	<i>UPS, FedEx, or other delivery service does not deliver the vaccine or does not deliver in a timely manner.</i>
<b>Abuse:</b>	<i>Provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care.</i>
<b>Fraud:</b>	<i>An intentional deception, or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person</i>

This document will serve as the Missouri Department of Health and Senior Services protocol for management of incidents that result in loss of vaccine supplied by Missouri Vaccines for Children (VFC) Program. The action taken by the VFC Program will depend on the category of the vaccine loss. For the purpose of this document, wasted vaccines fall under three categories:

**Category 1 – Non-Preventable Loss**

**Category 2 – Non-Compliance**

**Category 3 – Negligence**

**Note: In the event that children may have been vaccinated with expired or otherwise non-viable vaccine, the VFC program staff will provide guidance to clinic staff to make appropriate re-vaccination plans.**

#### **Standard Plan of Action for Vaccine Loss**

Provider is to contact the VFC Program at **(800) 219-3224** and the vaccine manufacturer(s) as soon as the situation is discovered and explain the circumstances to the representatives. Be prepared to furnish the following information:

- Last known temperature of the refrigerator/freezer and the date and time of that reading;
- Current temperature of the refrigerator/freezer;
- Duration of time the vaccines were stored out of recommended temperature range, lot numbers and expiration dates of all vaccines in question, number of doses, and manufacturer.

Provider will submit written strategies to prevent future misuse/abuse of VFC vaccine to the VFC Program.



**If the vaccines are determined to be viable, but the power to the office has not been restored or the refrigerator is still in disrepair, the provider must enact their Vaccine Emergency Plan. Vaccines must be transported immediately to an alternate refrigerator/freezer.**

### **Category 1 – Non-Preventable Loss**

Vaccine loss due to non-preventable circumstances, such as:

- Area power outages due to severe weather or other unavoidable and unanticipated causes.
- Refrigerator/freezer failure – unavoidable or unanticipated. (Refer to your refrigerator manufacturers manual and CDC's Vaccine Storage and Handling toolkit at: <http://www2a.cdc.gov/nip/isd/shtoolkit/splash.html>)
- Transport company error (i.e., FedEx, UPS, etc.).

**\*\*\*Note: Failure of the provider to notify VFC of a change in office hours or address will not be considered a transport company error. \*\*\***

If the vaccines in question are not salvageable, the VFC program staff will advise the provider concerning return of the wasted vaccines. As soon as power is restored, the provider should monitor and provide the VFC office with temperature logs for 3 days. If the refrigerator or freezer has been replaced, notify the VFC Program so that a program representative can certify the refrigerator/freezer. A determination will be made when replacement vaccines will be shipped to the provider.

### **Category 2 – Vaccine Loss Due to Non-Compliance**

Vaccine loss due to non-compliance is defined as:

1. VFC vaccine not accounted for per VFC Program requirements.  
Examples include, but are not limited to:
  - Failure to document doses administered on usage log;
  - Failure to document patient eligibility on usage log;
  - Failure to report inventory;
  - Inaccurate reporting of inventory;
  - Failure to report expired/wasted vaccine.
2. VFC vaccine knowingly administered to children who do not meet VFC Program eligibility criteria.
3. Accepting reimbursement from insurance companies or patients for VFC vaccine as evidenced by:
  - Administering VFC vaccine to a child and subsequently billing the child's insurance for the cost of the vaccine;
  - Charging the patient for the cost of the vaccine;
  - Charging a Medicaid recipient any fee at all.

### **Additional Plan of Action for Non-Compliance wastage:**

If a provider is found to be in violation of written VFC policies, the action taken will depend upon the policy violated as follows:

1. Vaccine unaccounted for in usage reports.

- The provider must report vaccine usage and inventory to the VFC Program per VFC Program guidelines. Follow-up visits by VFC program representatives will be conducted as determined by VFC Program.
- The provider must develop strategies to reduce vaccine loss, which may include, but are not limited to the following:
  - Vaccine medication log;
  - Accountability on weekly basis;
  - Rotation of staff responsible for vaccine accountability;
  - Review intake sheets.

***\*\*\*Note: Upon receipt of written notification from the provider, any infractions or continued administration of VFC supplied vaccine to children not eligible for VFC will result in decreased vaccine shipments, suspension or termination from the VFC Program.\*\*\****

2. Knowingly administering VFC vaccine to children who do not meet VFC Program eligibility criteria, accepting reimbursement from insurance companies or charging patients for VFC supplied vaccine is paramount to fraud and/or abuse.

***\*\*\*Note: Fraud and abuse cases will be forwarded to the appropriate authorities for investigation and potential prosecution.\*\*\****

The VFC Program may require additional information including, but not limited to:

- VFC eligibility screening records;
- Medicaid billing records;
- Tally records.

### **Category 3 – Negligence**

Negligence is defined as loss of vaccine on the part of the provider/clinic staff. The following situations qualify in this category:

1. Vaccine stored improperly (i.e., refrigerating vaccine that should have been frozen, vaccine left out of freezer or refrigerator, or freezing vaccine that should have been refrigerated).
2. Refrigerator or freezer unplugged or electrical service interrupted (circuit breaker).
3. Door of refrigerator or freezer left ajar resulting in unit temperatures outside the acceptable range.

4. Improper maintenance of recommended refrigerator and freezer temperatures.
5. Failure to properly read and record refrigerator(s) and freezer(s) temperatures, and/or take immediate corrective actions when temperatures are out of appropriate range.
6. Failure to properly train back-up personnel on storage and handling protocol.
7. Pre-drawing or pre-mixing vaccine, then not administering in accordance with vaccine manufacturer/CDC recommendations.
8. Transporting vaccine inappropriately (not using ice packs or dry ice), thus not maintaining the cold chain.
9. Failure to notify the VFC Program when provider office hours change or the practice moves, resulting in vaccines being undeliverable and consequently becoming non-viable.
10. Vaccine expired due to failure of the provider to notify the VFC Program three months prior to expiration date so that vaccine could be transferred; and/or
11. Failure to rotate stock appropriately.

**Additional Plan of Action for Negligence Wastage:**

**The VFC program staff will determine disposition of non-viable vaccine. The provider may be required to purchase replacement vaccines, if it is determined that the loss was due to provider negligence.**

**When replacement of vaccine is required:**

1. The provider will submit to the VFC Program a written report of the incident within 10 business days that describes the circumstances and the steps taken to ensure that vaccine is protected in the future.
2. The provider must mail or fax invoices and a completed VFC Vaccine Replacement form to the VFC Program within 10 business days after receipt of replacement vaccine.
3. When revaccination of children is necessary, the provider must prepare and submit to the VFC Program a listing of all children needing revaccination within 10 business days.
4. The assigned VFC County Liaison will verify replacement of the vaccines and documentation of revaccination of all affected children within 90 days of the incident.
5. The assigned VFC field representative will conduct a follow-up visit within 6 months of the incident to monitor vaccine storage and handling policies.
6. Wasted vaccine that is acceptable for return (vaccines, in their original vials or pre-filled syringes only, no used syringes, syringes you filled but did not use, or multi-dose vials with the cap removed) must be sent to McKesson Specialty as directed on the VFC Vaccine Return Packing Slip. This vaccine will be returned to the manufacturer for excise tax credit for purchase of additional vaccines.

**When replacement of vaccine is not required:**

1. The provider will submit to the VFC Program a written report of the incident within 10 business days that describes the circumstances and the steps taken to ensure that vaccine is protected in the future.

2. Vaccine shipments will be resumed upon receipt of the aforementioned letter. The assigned VFC field representative will conduct a follow-up visit within 6 months of the incident to monitor vaccine storage and handling policies.
3. Wasted vaccine that is acceptable for return (vaccines, in their original vials or pre-filled syringes only, no used syringes, syringes you filled but did not use, or multidose vials with the cap removed) must be sent to McKesson Specialty as directed on the VFC Vaccine Return Packing Slip. This vaccine will be returned to the manufacturer for excise tax credit for purchase of additional vaccines.

**I have read the Missouri Vaccines for Children Vaccine Loss and Replacement Protocol**

**(Please print)**

**Provider Name:** \_\_\_\_\_ **Provider #** \_\_\_\_\_

**Address:** \_\_\_\_\_

\_\_\_\_\_

**Telephone:** \_\_\_\_\_ **Fax:** \_\_\_\_\_

**Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

Sign and return to Missouri VFC Program

Fax to: 573-526-5220

Or mail to: VFC Program

Missouri Department of Health & Senior Services  
930 Wildwood Dr., P.O. Box 570  
Jefferson City, Missouri 65102-0570

## Emergency/Power Outage Plan (template)

Person Responsible \_\_\_\_\_ Phone # \_\_\_\_\_ Cell # \_\_\_\_\_

Secondary Person \_\_\_\_\_ Phone # \_\_\_\_\_ Cell # \_\_\_\_\_

### **KEEP ALL REFRIGERATOR AND FREEZER DOORS CLOSED** (*unless moving vaccines*)

#### **Mechanical Failure / Improper Temperature:**

- If alternative storage is available within your facility, transfer vaccine to that storage unit.
- Prior to transporting vaccine, record the temperature of the refrigerator(s) and freezer(s). Place a certified calibrated thermometer with vaccine to record temperature during transit.

#### **Power Outage / Natural Disaster:**

- If the building has lost electrical power, check with building maintenance. If a generator is available, ensure that the generator is operational and has been activated.
- If alternative storage with reliable power sources is available, transfer to that facility can be considered.
- Follow instructions for Alternate Off-Site Storage (see below).

#### **Alternate Off-Site Storage:**

- Contact your alternate facility listed below to notify them of your situation and the need to store vaccine at their location.
- Prior to transporting vaccine, record the temperature of the refrigerator(s) and freezer(s). Place a certified calibrated thermometer with vaccine to record temperature during transit.
- Transport the vaccine following the proper cold chain procedures for storage and handling.

\*For all situations where vaccines may be compromised, isolate and maintain vaccines at appropriate temperature; do not administer or discard vaccine until you contact the VFC Program at (800) 219-3224.

#### **Emergency Contact List:**

Electric Company: \_\_\_\_\_

Refrigerator Repair Company: \_\_\_\_\_

Building Maintenance: \_\_\_\_\_

Temperature Alarm Monitoring Company: \_\_\_\_\_

Alternate Storage Facility: \_\_\_\_\_ Phone # Day \_\_\_\_\_

Contact Name: \_\_\_\_\_ Evening # \_\_\_\_\_

Other: \_\_\_\_\_

#### **Emergency Supplies and Location:**

Flash Lights and Spare Batteries

Location of all storage units in facility

Circuit Breakers

Packing Materials: Styrofoam cooler, cold packs, insulating materials (refrigerator vaccines); dry ice (freezer vaccines) where available: \_\_\_\_\_ Phone # \_\_\_\_\_

Keys (if applicable)

#### **Post Event:**

Store vaccine within a working refrigerator/freezer marked "DO NOT USE" Gather the following information:

- What happened i.e. Power outage
- Which vaccines were involved, including number of doses, lot number, and expiration date.
- Minimum/Maximum temperature and how long the vaccine was exposed to these temperatures.

**Contact the VFC Program at (800) 219-3224 for further vaccine instructions**

## Instructions for Emergency/Power Outage Plan (template)

All VFC providers must submit an Emergency/Power Outage Plan to the Missouri Vaccines for Children program. This plan should be updated annually and reviewed by all staff with vaccine storage and handling responsibility. Please use the emergency plan template provided or develop one of your own and submit with your reenrollment.

1. Designate two people responsible for vaccine storage and security.
2. Ensure staff are aware of the correct storage temperature for vaccine.

Unit	Fahrenheit	Celsius
Refrigerator	35° - 46° F	2° - 8° C
Freezer	5° F or colder	-15° C or colder

3. Record the brand, model #, and serial number for each refrigerator/freezer unit.
4. Ensure emergency contact list is updated with current information.
5. Include detailed information regarding location of emergency supplies, i.e. room number where items are located.
6. Ensure all staff are aware of these emergency procedures and their location.

**Missouri VFC staff will ask for a copy of your emergency plan during on-site visits. The emergency plan must be returned with your reenrollment packet.**

**If you have further questions, please call the Immunization program at (800) 219-3224.**

## Provider Refrigerator and Freezer Information Sheet

Please complete the following table for all refrigeration units storing VFC vaccine. Using the legend below, indicate the type of each refrigerator and freezer in your office, list the location (e.g. room number, lab, office name etc.), and the type of certified thermometer being used in the unit in the table below. If you need additional space please copy and use as 2<sup>nd</sup> page. If you have questions contact Charlotte Sims Higgins at 573-526-7967.

### Storage Unit Types:

- A** = Household refrigerator/freezer unit  
(Must have separate doors and two separate temperature controls)
- B** = Stand-alone refrigerator
- C** = Stand-alone freezer
- D** = Purpose built refrigerator- large unit (e.g. Helmer)
- E** = Purpose built refrigerator- under the counter

### Certified Thermometer Types:

- A** = Digital with minimum-maximum capability
- B** = Digital without minimum-maximum capability
- C** = Fluid-filled
- D** = Other: \_\_\_\_\_

Unit Type (Letter)	Unit Size (Cubic Feet)	Does the unit have an alarm? *Yes or No	Location of Unit	Thermometer Type (Letter)

\*How is your clinic notified of out of range temps? \_\_\_\_\_

Facility/Clinic Name: \_\_\_\_\_ PIN Number: \_\_\_\_\_

Address: \_\_\_\_\_

Additional Comments: \_\_\_\_\_

# Vaccines for Children Fahrenheit (F) Temperature Log

Document temperatures twice daily and maintain temperature logs on file for a minimum of three (3) years									LOCATION or NUMBER: (Refrigerator) _____ (Freezer) _____								
Clinic Name: _____									Month/Year _____ PIN _____ (Required)								
REFRIGERATOR (Temperature Range not less than 35° to 46° F) (Optimum Temperature 40° - 42° F)									FREEZER (Temperature Range is 5° F or Less)								
Day of Month	Time: AM	Staff Initials	Actual Temperature	Are Temps in Range? (Yes/No)	Time: PM	Staff Initials	Actual Temperature	Are Temps in Range? (Yes/No)	Time: AM	Staff Initials	Actual Temperature	Are Temps in Range? (Yes/No)	Time: PM	Staff Initials	Actual Temperature	Are Temps in Range? (Yes/No)	Review & Signature of VFC Contact - Weekly
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If temperatures are not in range TAKE ACTION and DOCUMENT the action taken.									VFC Office Contact <b>MUST</b> Review and Initial Temperature Log Weekly								
<b>Instructions:</b> All staff responsible for checking temperatures <b>must be trained</b> to properly read the thermometer in each storage unit. In each of the corresponding columns across the page the staff person checking the temperature is to record the time, initial, record the temperature, determine if temperature is within range, and document <b>yes</b> it is in range or <b>no</b> it is not in range in the appropriate column. If the temperature is not in range <b>take action</b> and <b>document</b> the actions taken. The clinic VFC coordinator is to review the temperature log on a <b>weekly</b> basis to determine that proper protocols/documentation was followed and sign-off in the column of the corresponding day the review was completed. Note: Colder is <b>NOT</b> better for refrigerator temperatures.																	



### Vaccines for Children Celsius (C) Temperature Log

Document temperatures twice daily and maintain temperature logs on file for a minimum of three (3) years										LOCATION or NUMBER: (Refrigerator) _____ (Freezer) _____									
Clinic Name: _____										Month/Year _____ PIN _____ (Required)									
REFRIGERATOR (Temperature Range not less than 2° to 8° C) (Optimum Temperature 4° C)										FREEZER (Temperature Range is -15° C or Less)									
Day of Month	Time: AM	Staff Initials	Actual Temperature	Are Temps in Range? (Yes/No)	Time: PM	Staff Initials	Actual Temperature	Are Temps in Range? (Yes/No)		Time: AM	Staff Initials	Actual Temperature	Are Temps in Range? (Yes/No)	Time: PM	Staff Initials	Actual Temperature	Are Temps in Range? (Yes/No)	Review & Signature of VFC Contact - Weekly	
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If temperatures are not in range TAKE ACTION and DOCUMENT the action taken.										VFC Office Contact <b>MUST</b> Review and Initial Temperature Log Weekly									
<b>Instructions:</b> All staff responsible for checking temperatures <b>must be trained</b> to properly read the thermometer in each storage unit. In each of the corresponding columns across the page the staff person checking the temperature is to record the time, initial, record the temperature, determine if temperature is within range, and document <b>yes</b> it is in range or <b>no</b> it is not in range in the appropriate column. If the temperature is not in range <b>take action</b> and <b>document</b> the actions taken. The clinic VFC coordinator is to review the temperature log on a <b>weekly</b> basis to determine that proper protocols/documentation was followed and sign-off in the column of the corresponding day the review was completed. Note: Colder is <b>NOT</b> better for refrigerator temperatures.																			

# VACCINE COLD CHAIN PROTOCOL

## MISSOURI VACCINES FOR CHILDREN PROGRAM

### **\*\*\*POST IN A CONSPICUOUS PLACE\*\*\***

#### *Required Temperatures:*

##### *Refrigerator:*

*35-46 Degrees Fahrenheit*

*2-8 Degrees Celsius*

##### *Freezer:*

*5 Degrees Fahrenheit or below*

*-15 Degrees Celsius or below*

***“Maintaining the cold chain,”*** means keeping vaccines at the recommended temperature. The cold chain begins at the manufacturer, extends to the distributor, and continues at the provider until the vaccine is administered. Proper vaccine temperature must be maintained during transit and at every link in the chain to ensure its viability. The importance of maintaining the cold chain cannot be overstated. When the cold chain is not maintained, the vaccine may cease to be effective and will not provide protection from disease. **Any vaccine suspect of cold chain violation should be segregated from viable vaccine and NOT USED until the manufacturer determines viability.**

The **Vaccine Cold Chain Protocol** provides vaccine handling guidelines and action steps for health care providers in the event of a vaccine cold chain failure.

***Cold chain failure occurs when there is a break in any link of this chain.*** Cold chain failure may occur due to a power outage, equipment failure, staff error, etc. To prevent vaccine cold chain failure, it is essential to have properly functioning equipment, appropriately trained staff, clearly written procedures and easily accessible emergency operating protocols for handling vaccines.

#### **Immunization Providers Utilizing Vaccine Supplied by the VFC Program shall:**

- Develop and maintain a current written Vaccine Emergency Plan, providing guidelines to ensure vaccine cold chain maintenance to include:
  - Identification of an alternative storage facility (i.e., hospital, packing plant, local public health agency, nursing home, fire department, etc.) with back-up power (generator) where the vaccine can be stored and monitored during a power failure;
  - Identification of staff responsible to pack and move vaccine during an emergency;

- Maintenance of a supply of appropriate packing materials (insulated containers; the type vaccines are shipped in not soft side or high peaked, gel/ice packs, facility where dry ice will be purchased, etc.);
- Identification of transportation to move vaccine to a secure storage facility during an emergency;
- Establishment of procedures to monitor vaccine temperature during transport to confirm its viability with the manufacturer upon its return.

Policies/procedures will be available for review by program representatives as requested. A template is attached for use in preparing a Vaccine Emergency Plan (attached).

**Protocol for Suspected Vaccine Cold Chain Failure, the Provider shall:**

- **Within 24 hours:**
  - Inventory all vaccines determined to have been stored at inappropriate temperatures. They should be labeled “**DO NOT USE.**” Store potentially compromised vaccines at proper refrigerator/freezer temperatures while assessing viability.
  - Contact the VFC Program at (800) 219-3224. Be prepared to provide:
    - **Ambient room temperature;**
    - **Vaccine storage unit temperature;**
    - **Estimated duration of event;**
    - **Vaccine name;**
    - **Lot number;**
    - **Expiration date;**
    - **Number of doses at risk.**
- **The VFC program representative will investigate and determine what to do with the vaccine, and the provider will be given instructions on returning vaccine for credit.**

**Protocol for Confirmed Vaccine Cold Chain Failure, the Provider shall:**

- **No later than 24 hours of the confirmed cold chain failure:**
  - Notify the VFC Program.
  - Contact the vaccine manufacturer for guidance and provide the following information:
    - **Ambient room temperature;**
    - **Vaccine storage unit temperature;**
    - **Estimated duration of event;**
    - **Vaccine name;**
    - **Lot number;**
    - **Expiration date;**
    - **Number of doses lost.**

- Return non-viable vaccines (full, unopened vials only) to the VFC vaccine distributor McKesson Specialty Distribution using vaccine return packing slip within 15 days.
- Review patient records to identify persons receiving vaccines during the identified cold chain failure periods as deemed necessary by the VFC Program and/or the manufacturer.
- Compile and submit a Corrective Action Plan to the VFC Program outlining the steps to identify, recall, and revaccinate persons within one week.
- Contact identified persons and/or appropriate parent/guardian by telephone or written correspondence with the following information within 30 days of approval of the Corrective Action Plan.
  - **Purpose of recall**
  - **Need for revaccination**
  - **Information about available clinics and times for revaccination**
- Schedule clinics and appointments to revaccinate persons vaccinated during the cold chain failure event as identified in the Corrective Action Plan.
- Document appropriate vaccination information on the person's immunization record or provide an immunization record with the appropriate vaccination information at the time of revaccination.
- Instruct the appropriate parent/guardian of a revaccinated child to provide revaccination information immediately to the child's school and/or childcare facility.
- Keep an ongoing log with the following:
  - Number of persons revaccinated; and
  - Number of doses and date of each vaccine administered.

Submit status report **each Monday for the preceding week** to the VFC Program. The report must include:

- Names of patients revaccinated
- Vaccines administered
- Documentation of parental refusal to revaccinate

Provide proper vaccine storage and handling guidelines and vaccine administration protocols to each new employee, continually review and document this information with the staff to assure optimal cold chain practices